

## **REMARKS**

Claims 49, 53, 57, 69, 70, 73 and 83 were pending in this application.

Claims 49, 57 and 73 have been amended to recite that the genetic alteration is a deletion within the NS1 gene. Support for the amendment can be found in the specification as originally filed at page 16, line 30 to page 17, line 4. Support can also be found in U.S. Application serial number 08/316,439, filed September 30, 1994, (now U.S. Patent No. 5,840,520; (the "'520 Patent'")) from which the present application claims benefit of priority. In particular, the '520 Patent provides support for the present amendment at col. 48, *ll.* 8-11; col. 14, *ll.* 47-52; and Section 7.2.1, beginning at col. 37, *l.* 49. A more detailed discussion of the written description and enabling support of the amended claims in the '520 Patent can be found below.

No new matter has been introduced by this amendment. Claims 49, 53, 57, 69, 70, 73 and 83 will be pending upon entry of the present amendment.

## **SUMMARY OF THE SUBSTANCE OF THE INTERVIEW**

Applicants thank Examiner Zachariah Lucas and Supervisory Examiner Bruce Campbell for the courtesy extended during the telephonic interview conducted on July 24<sup>th</sup>, 2008 ("the Interview"). Also present at the Interview were representatives for Applicants Drs. Jacqueline Benn and Sebastian Martinek of Jones Day.

Three applications were discussed during the Interview: the present application; U.S. application serial number 11/389,618; filed March 24, 2006 (the "'618 Application"), and U.S. application serial number 11/079,002, filed March 11, 2005. In particular, Applicants' right to claim benefit of priority from U.S. Application serial number 08/316,439, filed September 30, 1994 (now the "'520 Patent") in these applications was discussed. Although the discussion during the Interview focused on the '618 Application, Examiner Lucas and Dr. Benn agreed that the priority issue is substantially the same in all three applications. The summary of the interview below has been adjusted accordingly.

Dr. Benn stated that Applicants propose to amend the claims to recite "deletion *in* the NS1 gene," as opposed to "deletion *of* the NS1 gene." The Examiner stated he would not consider an amendment after a final Office Action in the absence of a Request for Continued Examination.

Dr. Benn stated that support for substitutions, deletions and additions in the RSV genome can be found in the '520 Patent in Example 9, column 48, lines 8-14. In addition, it was well known in the art by the priority date of September 30, 1994 that the RSV genome included the NS1 gene. Dr. Benn cited Johnson and Collins, 1989, J. Gen. Virol.; 70:1539-47, as an example to demonstrate that the existence of the NS1 gene in RSV was well-known in the art in 1994. Dr. Benn also stated that methods to test the ability of RSV with deletions in the NS1 gene to replicate can be found in Example 9.2. of the '520 Patent. Further modifications of the NS1 gene in influenza are illustrated throughout the specification of the '520 Patent (for example, column 18, lines 50, to column 19, line 19; and column 37, lines 50-67).

The Examiner stated that Applicants' evidence, arguments, and any amendments would be considered once presented in a response under 37 C.F.R. § 1.114 to the outstanding Office Action. The present amendment and the remarks herein reflect the discussion during the Interview.

#### **The Rejection Under 35 U.S.C. § 102 Over Murphy Should be Withdrawn**

Claims 49, 57, 70 and 73 have been rejected under 35 U.S.C. § 102(e) as anticipated by Murphy *et al.* (U.S. Patent No. 5,993,824; "Murphy"). In particular, the Examiner states that no support for a deletion of the NS1 gene could be found in Applicants' parent application serial number 08/316,439, filed September 30, 1994 (now U.S. Patent No. 5,840,520; the "'520 Patent"). Applicants disagree as set forth in detail below. Because Applicants are entitled to their priority of September 30, 1994, Murphy, with its July 15, 1997 filing date, and priority dates of May 23, 1997, May 9, 1997, and July 15, 1996, is not prior art against the present application.

#### **LEGAL STANDARD**

To be entitled to benefit of priority, the priority application must disclose the claimed invention in compliance with 35 U.S.C. § 112, first paragraph (35 U.S.C. § 120).

#### **WRITTEN DESCRIPTION**

The test for sufficiency of written description is whether the disclosure of the application 'reasonably conveys to the artisan that the inventor had possession' of the

claimed subject matter. *In re Kaslow*, 707 F.2d 1366, 1375, 217 U.S.P.Q. (BNA) 1089, 1096 (Fed. Cir. 1983); accord *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563; *see also*, *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575, 227 U.S.P.Q. (BNA) 177, 179 (Fed. Cir. 1985). The Court of Appeals for the Federal Circuit has repeatedly considered the written description requirement and consistently found that exacting detail is not necessary to meet the requirement:

If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if [not] every nuance of the claims is explicitly described in the specification, the adequate written description requirement is met. *In re Alton*, 76 F.3d 1168, 37 USPQ2d 1578 (Fed. Cir. 1996).

Furthermore, in accordance with the Guidelines, what is conventional or well known to one of skill in the art need not be disclosed in detail (*Id.* at p. 1105, column 3, *ll.* 39-41), and, where the level of knowledge and skill in the art is high, a written description question should not be raised. *Id.* at p. 1106, column 1, *ll.* 34-36. *See also* *Capon v. Eshhar*, 418 F.3d 1349, at 1357 (Fed. Cir. 2005).

## ENABLEMENT

The test for enablement is whether one reasonably skilled in the art could make or use the invention, without undue experimentation, from the disclosure in the patent specification coupled with information known in the art at the time the patent application was filed. *U.S. v. Telectronics Inc.*, 857 F.2d 778, 8 USPQ2d 1217 (Fed. Cir. 1988). In fact, well known subject matter is preferably omitted. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) ("a patent need not teach, and preferably omits, what is well known in the art."). Further, one skilled in the art is presumed to use the information available to him in attempting to make or use the claimed invention. *See Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941 (Fed. Cir. 1990) ("A decision on the issue of enablement requires determination of whether a person skilled in the pertinent art, using the knowledge available to such a person and the disclosure in the patent document, could make and use the invention without undue experimentation."). These enablement rules preclude the need for the patent applicant to "set forth every minute detail regarding the invention."

*Phillips Petroleum Co. v. United States Steel Corp.*, 673 F. Supp. 1278, 1291 (D. Del. 1991); see also *DeGeorge v. Bernier*, 768 F.2d 1318, 1323 (Fed. Cir. 1985).

### **The Claimed Methods Are Sufficiently Described In The '520 Patent**

The priority document provides written description for deletions within the NS1 gene. The disclosure of a vaccine or an immunogenic composition comprising an attenuated RSV with an NS1 deletion is found in the '520 Patent. The invention disclosed in the '520 Patent includes deletions to the RSV genome in order to produce vaccines (*see, e.g.*, column 44, lines 24-32). The priority document provides by way of example that modifications may be made to RSV, including deletions or additions within genes and/or regulatory domains of the RSV genome (*see, e.g.*, column 48, lines 8-14). Johnson and Collins, 1989, J. Gen. Virol.; 70:1539-47 ("Johnson"), concurrently submitted as reference C119 in the Supplemental Information Disclosure Statement dated July 30, 2008, teach that the NS1 gene was identified as part of the RSV genome prior to the priority date of September 30, 1994. Johnson at p. 1539, 4<sup>th</sup> to last line. In view of the common general knowledge that RSV contains an NS1 gene and the teaching in the '520 Patent that deletions can be made within the RSV genome, the '520 Patent provides sufficient written description support for the amended claims.

In addition, the '520 Patent teaches modification of the NS1 gene in influenza. See, *e.g.*, column 18, lines 50, to column 19, line 19; and column 37, lines 50-67. It is stated in the '520 Patent that the principles taught in the '520 Patent for influenza virus, are analogously applicable to, *e.g.*, RSV (col. 14, *ll.* 43-51).

### **THE CLAIMED METHODS ARE ENABLED**

The '520 Patent teaches how to construct recombinant viruses with deletions within the NS1 gene. Methods for rescuing recombinant RSV are taught in Section 9, beginning at col. 42, *l.* 50. The '520 also provides illustrative support for modifications in the genome of influenza but teaches that these principles are analogously applicable to RSV (*see* column 14, lines 38-58). Specifically, support is provided for modifications of the NS1 gene (*see, e.g.*, Section 7.2.1., beginning at column 37, *l.* 49). Once constructed, the '520 Patent teaches methods for testing the ability to infect and replicate of the resulting recombinant RSV with modified NS1 genes (*see, e.g.*, column 46, Section 9.2). Thus, no undue experimentation

would be required to make and use the recombinant RSV recited in the claims under consideration.

Taken together, the '520 Patent teaches RSV vaccines having deletions within the NS1 coding region. Thus, Applicants are entitled to a priority date of September 30, 1994, which predates the filing date of Murphy. Accordingly, Murphy is not prior art and the rejection under 35 U.S.C. § 102(e) over Murphy should be withdrawn.

**The Rejection Under 35 U.S.C. § 103 Over Murphy Should Be Withdrawn**

Claims 49, 53, 57, 69, 70, 73 and 83 are rejected under 35 U.S.C. § 103(a) over Murphy in view of Knipe et al. (U.S. Patent 7,223,411; "Knipe") and Inglis et al. (U.S. Patent 5,665,362; "Inglis"). As discussed above, Murphy is not prior art against the presently pending claims. Neither Knipe nor Inglis teaches or suggests recombinant RSV with a genetic alteration.

Thus, the rejection of claims 49, 53, 57, 69, 70, 73 and 83 under 35 U.S.C. § 103(a) over Murphy in view of Knipe and Inglis should be withdrawn.

**Provisional Double Patenting**

Claim 49 has been provisionally rejected under 35 U.S.C. § 101 as allegedly claiming the same invention as claim 24 of U.S. Patent Application No.: 11/690,957 (the '957 Application). Claim 24 in the '957 Application has been canceled in the Preliminary Amendment filed on July 18, 2008. Thus, the rejection of claim 49 under 35 U.S.C. § 101 over U.S. Patent Application No.: 11/690,957 should be withdrawn.

Claims 57, 70 and 73 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 24, 29, 31, 32, and 35 of the '957 Application. Claims 17, 24, 29, 31, 32, and 35 have been canceled in the '957 Application. Thus, the rejection of claims 57, 70 and 73 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 24, 29, 31, 32, and 35 of U.S. Application Serial No. 11/690,957 should be withdrawn.

Claims 53, 69 and 83 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 24, 29, 31, 32, and 35 of U.S. Application Serial No. 11/690,957 in view of Murphy (supra), Knipe (supra), and Inglis (supra). Claims 17, 24, 29, 31, 32, and 35 in the '957 Application have been canceled.

Thus, the rejection of claims 53, 69 and 83 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 24, 29, 31, 32, and 35 of U.S. Application Serial No. 11/690,957 in view of Murphy (supra), Knipe (supra), and Inglis (supra) should be withdrawn.

## CONCLUSION

Applicants respectfully request entry and consideration of the foregoing amendments and remarks. No new matter has been introduced. The claims are believed to be free of the art and patentable. Withdrawal of all the rejections and an allowance are earnestly sought. Please charge any additional fee that may be required in connection with this filing to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

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